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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,536	12/28/2004	Yoshikatsu Kodama	2004_2037A	2533

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EXAMINER	
TONGUE, LAKIA J	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 09/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/519,536	KODAMA ET AL.	
	Examiner	Art Unit	
	Lakia J. Tongue	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 2-7 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 2-7 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response filed on July 5, 2006 is acknowledged. Claims 2-6 and newly added claim 7 are pending and under consideration. Claim 1 has been canceled.

The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office Action.

Objections/Rejections Withdrawn

1. In view of applicants' response the objection to the disclosure for informalities on page 3, paragraph 3 is withdrawn.

2. In view of applicants' response the objection of claim 1 for informalities on page 3, paragraph 4 is withdrawn.

3. In view of applicants' response the rejection of claims 1 and 3-5 under 35 U.S.C. 102(b) as being anticipated by Reynolds et al on page 7, paragraph 6 is withdrawn.

4. In view of applicants' response the rejection of claims 1 and 3-5 under 35 U.S.C. 102(e) as being anticipated by Garzon et al on page 9, paragraph 7 is withdrawn.

5. In view of applicants' response the rejection of claim 6 under 35 U.S.C. 102(e) as being anticipated by Garzon et al on page 11, paragraph 8 is withdrawn.

6. In view of applicants' response the rejection of claim 6 under 35 U.S.C. 103(a) as being unpatentable over Reynolds in view of Garzon et al on page 12, paragraph 9 is withdrawn.

Objections/Rejections Maintained

7. Claims 4, 6 and newly added claim 7 under 35 U.S.C 112, first paragraph (scope of enablement) is maintained for the reasons set forth in the previous office action on page 3, paragraph 5.

The rejection is on the grounds that the specification, while being enabling for a method for treating chicken coccidiosis wherein the antibody is obtained from an egg of a chicken immunized with an antigenic outer membrane protein or an immunogenic fragment thereof having a common immunogenicity shared among sporozoite and merozoite of *Eimeria acervulina, Eimeria tenella,* and *Eimeria maxima* and is orally administered to a bird optionally in combination with a lactic acid bacterium and/or an antibody obtained from an egg of a chicken immunized with *Clostridium perfringens*, does not reasonably provide enablement for a method for preventing chicken coccidiosis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

A vaccine must by definition provide an immunoprotective response upon administration. The specification does not provide substantive evidence that the claimed composition is capable of inducing protective immunity against chicken coccidiosis. This demonstration is required for the skilled artisan to be able to use the claimed composition for their intended purpose of preventing coccidiosis. Without this demonstration, the skilled artisan would not be able to reasonably predict the outcome of the administration of the claimed composition, i.e. would not be able to accurately predict if protective immunity has been induced. The instant specification speaks to the treatment of chicken coccidiosis by way of increasing the average weight gain, food intake and decreasing the oocyst score etc. Applicant submits that the claimed composition is considerably effective and the above-mentioned factors are significantly improved (page 15, 2nd ¶ and table 1). The examiner has not seen an example in the specification where a pathogen free bird was administered the claimed composition and as a result the bird was protected from coccidiosis. Was the above-mentioned composition ever administered to a subject that was not infected with coccidiosis prior to the administration of the claimed composition? Where is the data showing the resulting protection?

The ability to reasonably predict the capacity of a single bacterial immunogen to induce protective immunity from in vitro antibody reactivity studies is problematic. Ellis exemplifies this problem in the recitation that "the key to the problem (of vaccine development) is the identification of the protein component of a virus or microbial pathogen that itself can elicit the production of protective antibodies"(page 572, second full paragraph). Unfortunately, the art is replete with instances where even well characterized antigens that induce an in vitro neutralizing antibody response fail to elicit in vivo protective immunity. See Boslego et al. wherein a single gonococcal pillin protein fails to elicit protective immunity even though a high level of serum antibody response is s induced (page 212, bottom of column 2). Accordingly, the art indicates that it would require undue experimentation to formulate and use a successful vaccine without the prior demonstration of vaccine efficacy.

Wallach et al (Passive immunization of chickens against *Eimeria maxima* infection with a monoclonal antibody developed against a gametocyte antigen, Infection and Immunity, 1990; 58(2): 557-62) discloses that the antigenic diversity of *E. maxima* is considered to be a major problem in the development of a vaccine against this species. This is based on the finding that an infection with one strain of *E. maxima* does not protect against challenge with a different strain (page 561, 2nd column).

Moreover, Dalloul et al (Poultry coccidiosois: recent advancements in control measures and vaccine development, Expert Rev. Vaccines, 2006; 5(1): 143-163) discloses that increasing evidence shows the magnitude of complexity involved in host immune responses to Eimeria. Additional basic research is needed to ascertain the detailed immunologic and physiologic processes mediating protective immunity. Lastly Dalloul et al discloses that critical resources are severely lacking, which make is difficult to fulfill timely progress (page 156, concluding remarks).

The Wands factors have been considered in the establishment of this scope of enablement rejection:

a. the quantity of experimentation necessary would be undue for the prevention of coccidiosis;
b. the amount of direction or guidance has not been presented;
c. the presence or absence of working examples displaying the protection/prevention of chicken coccidiosis has not been provided;
d. the nature of the invention is one that without specific guidance would be problematic;
e. the state of the prior art is one which states that additional basic research is needed to ascertain the detailed immunologic and physiologic processes mediating protective immunity;
f. the relative skill of those in the art: high;
g. the predictability or unpredictability of the art: unpredictable because critical resources are severely lacking making it difficult to fulfill timely progress ; and
h. breadth of the claims: broad.
Since the immune response is considered to be one of the most complex and unpredictable biological processes and in view of the prior art teachings and all of the above, it is determined that it would require undue experimentation to use the claimed composition for preventing chicken coccidiosis.

Applicant argues that 1) a Rule 132 Declaration of Dr. Yoshikatsu Kodama, containing a description of comparative experiments has been submitted herewith. Applicant's arguments have been fully considered and deemed non-persuasive.

With regard to Point 1, the examiner acknowledges the Rule 132 Declaration which was submitted with applicant's response, however, the declaration under Rule 132 is insufficient to overcome this rejection. The references cited in this rejection teach that one strain of E. maxima does not protect against challenge with a different strain. Moreover, the Declaration provided never challenged against Eimeria to demonstrate protection. Finally, it is not clear how a percent of rate maturity is related to *preventing* coccidiosis. In view of the response above the rejection is maintained.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 2-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejected claims are drawn to an anti-chicken coccidiosis composition for oral administration comprising an antibody obtained from an egg of a chicken immunized with an antigenic outer membrane protein or an immunogenic fragment thereof having a common immunogenicity shared among sporozoite and merozoite of *Eimeria acervulina, Eimeria tenella* and *Eimeria maxima* which are associated with chicken coccidiosis, and a lactic acid bacterium.

The claims are drawn to a vast genus of antigenic outer membrane proteins and immunogenic fragments thereof. To fulfill the written description requirements set forth under 35 USC § 112, first paragraph, the specification must describe at least a substantial number of the members of the claimed genus, or alternatively describe a representative member of the claimed genus, which shares a particularly defining feature common to at least a substantial number of the members of the claimed genus, which would enable the skilled artisan to immediately recognize and distinguish its members from others, so as to reasonably convey to the skilled artisan that Applicant has possession the claimed invention.

Moreover, the skilled artisan cannot envision the detailed structure of the encompassed proteins, regardless of the complexity or simplicity of the method of

isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The polypeptide itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404. 1405 held that: ...To fulfill the written description requirement, a patent specification must describe an invention and does so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines Inc. , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2datl966.

An adequate written description of the claimed antigenic outer membrane protein or an immunogenic fragment thereof, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for

obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993).

However, the specification has not provided an adequate showing of which antibodies bind to antigens based solely on their common immunogenicity from among different species. The specification does not provide a written description of the invention of claims 2-7. The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the "written description" inquiry, whatever is now claimed.

Therefore, absent a detailed and particular description of a representative number, or at least a substantial number of the members of the genus of antigenic outer membrane protein or an immunogenic fragment thereof, the skilled artisan could not immediately recognize or distinguish members of the claimed genus having preventive and/or reduced cellular and humoral immunogenicity. Therefore, because the art is unpredictable, in accordance with the Guidelines, the description of antigenic outer membrane protein or an immunogenic fragment thereof, is not deemed representative of the genus of immunogenic compositions to which the claims refer and hence do not meet the written description requirements.

Conclusion

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakia J Tongue whose telephone number is 571-272-2921. The examiner can normally be reached on Monday-Friday 7-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Mark Navarro can be reached on 571-272-0861. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LJT
9/14/06

MARK NAVARRO
PRIMARY EXAMINER